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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,252	07/08/2002	Tadanori Mayumi	MAYUMI=1	9722

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,252

Applicant(s)

MAYUMI ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,9,11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,9,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claims 1, 4, 5 have been amended, claims 3, 7, 10, 12 have been canceled by the amendment filed October 9, 2003.

Claims 1, 2, 4-6, 8, 9, 11, and 13 are pending for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. ' 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. ' 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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Claims 1, 2, 4-6, 8, 9, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 USC 103 as being unpatentable over either Fernandez (US Pat No. 5,820,879) or Dunn (WO 97/04747).

The claims are drawn to a slow-release composition comprising nanospheres that encapsulate a physiologically active substance and which are encapsulated in liposomes having fusogenic capability, wherein the nanospheres have a particle size of 10 – 600 nm, and to a delivery method of employing the composition. Fernandez and Dunn teaches the same throughout the disclosure, *e.g.*, abstract, column 2, lines 24-43, column 13, lines 26-42, column 20 through column 21, column 33 (Fernandez); pages 3-4, page 5, pages 6-7, example 3, and page 19 (Dunn). Since both Fernandez and Dunn teaches that liposomes act to fuse or contact the cell membrane of a target cell and to piggyback its contents (nanoparticles encapsulating a biologically active substance) into the cell, the liposomes of the references exhibit a fusogenic capability. To the extent that the claims embrace an addition to numerous known fusogenic substances to the surface of the liposomes of the references so as to increase their bioadhesiveness or fusogenic capability, it would have been obvious to one of ordinary skill in the art that addition(s) of well-know bioadhesive adjuvants and/or fusogenic substances, as evidenced by the teaching of the exemplified Dunn and/or art cited in the as-filed specification (p. 2 bridging p. 3) are conventional, and thus, one would have been motivated to employ such adjuvants and/or substances to make surface-modified liposomes thereby increasing the efficiency

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of liposomes as carriers to transport biologically active substances across the extracellular membrane of target cell.

Thus, the claimed invention is anticipated by the cited references, or in the alternative, is *prima facie* obvious, over the prior art as a whole.

Claims 1, 2, 4-6, 8, 9, 11, and 13 are rejected under 35 USC 103 as being obvious over Fernandez or Dunn, taken with Dzau (US Pat No. 5,631,237)

The claims are drawn to a slow-release composition comprising nanospheres that encapsulate a physiologically active substance and which are encapsulated in liposomes having fusogenic capability conferred by a reaction with a Sendai virus. The reaction containing limitation is not necessarily limited to what is disclosed in the specification on page 7, line 28 to page 8, line 3, and page 10, and lines 13-15, e.g., the reaction conferred by shaking a solution of the liposomes with Sendai virus at 37° C. The claimed nanospheres have a particle size of 10 – 600 nm. Methods of employing the claimed composition for delivery are also claimed. Other than the limitation of employing a reacted Sendai virus in order to enhance the fusogenic capability of liposomes employed in a slow-release composition containing nanoparticles, Fernandez and Dunn teaches the same throughout the disclosure, e.g., abstract, column 2, lines 24-43, column 13, lines 26-42, column 20 through column 21, column 33

(Fernandez); pages 3-4, page 5, pages 6-7, example 3, and page 19 (Dunn).

To the extent that the Fernandez and Dunn references are silent over the limitation which recites that a Sendai virus is reacted with a liposome prior to

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encapsulation so as to increase their fusogenic capability of the , Dzau teaches that a fusogenic liposome conferred by a reaction with a Sendai virus is effective fusion of the employed liposomes to cell targets and efficient delivery of a biologically active agent to a target cell, column 6, lines 60-64, column 16, lines 40-45, column 17, lines 17-20, column 19, lines 54-60, and column 31, lines 45-51. Thus, one of ordinary skill in the art would have reasonably recognized from the teaching of Dzau that fusogenically Sendai virus protein bound liposomes conferred by a reaction is effective for use in enhancing the delivery and fusion of any therapeutic/biologically active agent through cellular targets.

In view of the combined cited references as a whole, it would have been obvious for one of ordinary skill in the art to react a Sendal virus to the encapsulated liposomes of Fernandez or Dunn so as to increase the fusion of the delivered liposomes through any cellular target. One would have been motivated to do so because Dzai teaches that an application of a Sendai virus as a component of fusogenic liposomes in delivery of a biologically active agent through any cellular target would enhance a functional retargeting and fusogenic capability of liposomal carrier, thereby enhancing the fusion through a cellular target, and the subsequent delivery/activity of a carried therapeutic agent in the cellular target.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant' response, pages 6-10 of the latest response, has been moot in view of the new ground of the rejection.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
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DAVE TRONG NGUYEN
PRIMARY EXAMINER